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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,499	11/21/2001	Raman K. Bakshi	20385YDA	4343

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EXAMINER
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SEAMAN, D MARGARET M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 12/02/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/990,499

Applicant(s)

BAKSHI ET AL.

Examiner

D. Margaret Seaman

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 39-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

### DETAILED ACTION

This application was filed 11/21/2001 and is a DIV of 09/585,111 (US Patent #6,350,760) which claims benefit of Provisional Applications 60/137,477 (6/4/1999) and 60/169,209 (12/2/1999). Claims 39-75 are before the Examiner.

#### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. The rejection of claims 39-75 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,350,760, is *upheld*. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of the patent are fully encompassed by the instant claims. Also, the compound of line 40 column 82 of the patent is the cis/trans stereoisomer of the elected species.

*Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 39-75 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is *upheld*. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to choose a compound that is outside the scope of the instant formula (I) (see page 7). No structural characteristics of an agonist are provided nor is there any indication that applicant had possession of any such agonist other than the compounds of formula (I) which have already been patented (see the above double patenting rejection). The specification fails to disclose any particular structure for the claimed receptor agonists. Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention, the claims fail to comply with the written description requirement.

5. The rejection of claims 39-75 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is *upheld*. The specification does not enable the ordinary artisan to choose a compound that is other than patented in the parent case, namely a substituted isoquinoline. The entire specification is drawn to substituted isoquinoline compounds of formula (I) that are MC-4R agonists. There is no teaching in the specification that would lead one of ordinary skill in the art to compounds other than formula (I). Without a teaching of what other compounds to pursue, the specification is seen to be lacking in enablement for the instant claims. Without guidance, the instant specification is an invitation to test any and all known and unknown compounds for their ability to bind selectively and be agonists of MC-4R.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention

based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

**1) *The breadth of the claims:*** The claims are drawn to treatment of sexual dysfunction in a male subject with any compound that is a MC-4R agonist.

**2) *The nature of the invention:*** The invention is drawn to treatment of male erectile dysfunction by using a MC-4R agonist wherein the binding of the compound to MC-4R is characterized by an IC50 of less than 30 nanomolar and the binding of the compound to the human MC-1R is characterized by an IC50 greater than 30 nM..

**3) *The state of the prior art:*** The prior art discusses treating male erectile dysfunction by using certain families of compounds that are MC-4R, MC-3R, MC-2R, MC-1R, and MC-5R agonists. However, the art is silent about what other compounds or families of compounds might be MC-4R agonists.

**5) *The level of predictability in the art:*** It has not been shown that there is any level of predictability in the art.

**6) *The amount of direction provided by the inventor:*** The inventor has provided direction only for the compounds of formula (I) treating male erectile dysfunction. However, there is no direction provided by the inventor to treat male erectile dysfunctions with any compound that is other than a compound of formula (I).

**7) *The existence of working examples:*** The only working examples of MC-4R agonists are of formula (I). The specification does not provide any other working examples other than the compounds of formula (I) that have already been patented.

*8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure:* The experimentation needed to make or use the instant invention is undue. There is no guidance of what kind of compound to choose other than of formula (I) to be a MC-4R agonist. The ordinary artisan would be forced to pick compounds at random from all known and unknown compounds to test them randomly to see if they are MC-4R agonists having the other parameters that are disclosed in the claims. This is very extensive and undue experimentation.

Taking these into consideration, it is not seen where the instant specification enables the ordinary artisan to make and/or use the instant invention.

Further, the instant specification does not provide any guidance with respect to how to choose a compound outside of the scope of the formula (I) that would fulfill the requirements for the instant claims. There is no description of the identifying characteristics for recognizing that a compound is a candidate for the instant claims. No structural characteristics of such compounds are provided, nor is there any indication that applicant has possession of any such compound outside of the compounds of formula (I). The specification fails to disclose any particular structure for the compound that would treat male erectile dysfunction other than formula (I). The specification does not provide any guidance or any working examples in this unpredictable art, and thus the artisan would have been unable to prepare the claimed treatment. An assay for finding a product is not equivalent to a positive recitation of

how to make a product. These claims fail to meet the enablement requirement for the "how to make" prong of 35 USC 112, first paragraph.

Applicants argue that direction and guidance is given. Critical inventive parameters of selective activation of the MC-4R receptor is given. How to identify compounds that properly bind and function as agonists and how to evaluate their therapeutic properties in models is given.

However, an assay for finding a product is not equivalent to a positive recitation of how to make a product. No structural characteristics are provided of compounds that meet the instant claims. The compounds of formula (I) and how to treat using these compounds have already been patented in US Patent #6,350,760. Other than these compounds of formula (I), no other enablement is given. Applicant has not shown that they are in possession of the claimed invention.

### *Conclusion*

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

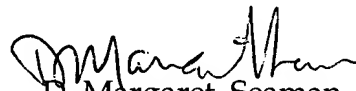
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 703-308-4528. On or about 29 January 2004, the Examiner will move to the new office location at the Carlyle Campus. The new phone number is expected to be 571-272-0694. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
D. Margaret Seaman  
Primary Examiner  
Art Unit 1625